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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/062,316	02/04/2002	Yaguang Liu		3984

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EXAMINER
FLOOD, MICHELE C

ART UNIT	PAPER NUMBER
1654	4

DATE MAILED: 02/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
10/062,316	Liu
Examiner	**Art Unit**
Michele Flood	1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Jan 6, 2003* .

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above, claim(s) *1-13, 17, and 26* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *14-16 and 18-25* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restriction

Applicant's election without traverse of Group IV, Claims 14-16 and 18-25, in Paper No. 3 is acknowledged.

Claims 14-16 and 18-25 are under examination.

Specification/Abstract

The abstract is objected to for the following informalities:

The abstract contains the abbreviations "PDG" and "DG" without setting forth the meaning of the terms. Abbreviations in the first instance of claims should be expanded upon with the abbreviation indicated in parentheses. The abbreviations can be used thereafter.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 14-16 and 18-25 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification lacks adequate written description guidance as to what plant ingredients comprise the instantly claimed "safe botanical drug". Applicant only refers to the plant ingredients as "Dang Gui containing soybean-liposomes (DGL)" and "LX-containing soybean-liposomes (LXL)", i.e., "Lan Xiang Xi containing soybean-liposomes". Further, based on a computer-assisted literature search, the overall state of the art does not appear to adequately teach any or all of such plant ingredients or preparations. For instance, a search on the term "Dang Gui" identifies "Dang Gui" as *Radix Angelica sinensis* or Chinese angelica root. However, a search on the term "Lan Xiang Xi" found no results. Accordingly, it is not known by the instant teachings what is the Latin genus-species names of the plants Applicant intends to direct the subject matter of the instantly claimed invention. Yet still, it is not known by the instant teachings if the leaves, stems, flowers, berries, roots, bark, and/or other part(s) of each of the two disclosed plant ingredients are being used to form the claimed therapeutic composition. The only

apparent guidance provided by the instant specification is on page 3, lines 15-29, which briefly discloses that the starting material of the plant ingredients are in the form of powder and that they are subjected to process steps of extraction. For example, on page 3, lines 28-29, under "Example 2 LX extraction", Applicant discloses "One kg of plant powder was extracted 5 L of water at room temperature for 12 hours. The powder of plant named Dryobalanops aromatica Gaerin or Wen E Shu was recovered by filtration." However, it is unclear as to what are the constituents of the "One kg of plant powder" that was extracted with 5 L of water. It is also uncertain as to what is the relation of "the powder of plant named Dryobalanops aromatica Gaerin or Wen E Shu" that was recovered by the process of filtration to "Lan Xiang Xi". However, as stated above, the specification fails to teach what is the Latin genus-species name of the plant ingredients comprising the claimed therapeutic composition or what part or parts of these plants are used in the making of the powders which are used in extraction processes for the making of the claimed therapeutic composition. Moreover, it is well known in the art that different parts of plants contain highly variable, distinct active ingredients therein, making the use of any and all parts of such plants highly unpredictable in terms of successfully preparing a composition having the therapeutic effects instantly disclosed and claimed.

Based on the lack of guidance provided by the instant specification and the overall state of the art, as well as the highly unpredictability in determining which plants or which plant part(s) contain particular active ingredients therein, it would take undue experimentation without a reasonable expectation of success for the skilled artisan to prepare a safe botanical drug having

the disclosed/claimed therapeutic effects from the two recited plant ingredients of "Dang Gui containing soybean-liposomes (DGL)" and "LX-containing soybean-liposomes (LXL)".

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 14-16 and 18-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 14, line 2, recites the abbreviation "LX-containing soybean-liposomes (LXL)". Abbreviations in the first instance of claims should be expanded upon with the abbreviation indicated in parentheses. The abbreviations can be used thereafter. For instance, the abbreviation "LX" should be expanded upon.

Claim 15 recites the limitation "the amount sufficient for treatment and prevention of malignant pleural effusion and cancer and enhancement immune function" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

Claim 18 is rendered vague and indefinite by the phrase "wherein said DGL used for enhancement of immune function and inhibiting oncogenes and cancer incidence" because it is unclear as to the subject matter Applicant intends to direct the invention. For

instance, the composition of claim 14 comprises both DGL and LXL; therefore, it is confusing as to why only the one ingredient is referred to by Applicant. Does only the ingredient of DGL have the claimed functional effect? The lack of clarity makes the metes and bounds of the claimed invention uncertain and very confusing.

Claim 19 is rendered vague and indefinite by the phrase "wherein said LXL used for inhibiting oncogenes" because it is unclear as to the subject matter Applicant intends to direct the invention. For instance, the composition of claim 14 comprises both DGL and LXL; therefore, it is confusing as to why only the one ingredient is referred to by Applicant. Does only the ingredient of LXL have the claimed functional effect? The lack of clarity makes the metes and bounds of the claimed invention uncertain and very confusing.

Claim 20 is rendered vague and indefinite by the phrase "wherein said LXL used for inducing differentiation of cancer cells" because it is unclear as to the subject matter Applicant intends to direct the invention. For instance, the composition of claim 14 comprises both DGL and LXL; therefore, it is confusing as to why only the one ingredient is referred to by Applicant. Does only the ingredient of LXL have the claimed functional effect? The lack of clarity makes the metes and bounds of the claimed invention uncertain and very confusing.

Claim 21 is rendered vague and indefinite by the phrase "wherein said LXL used for inhibiting cancer cells proliferation" because it is unclear as to the subject matter Applicant

intends to direct the invention. For instance, the composition of claim 14 comprises both DGL and LXL; therefore, it is confusing as to why only the one ingredient is referred to by Applicant. Does only the ingredient of LXL have the claimed functional effect? The lack of clarity makes the metes and bounds of the claimed invention uncertain and very confusing.

Claim 22 is rendered vague and indefinite by the phrase "wherein said LXL used for inducing apoptosis of cancer cells" because it is unclear as to the subject matter Applicant intends to direct the invention. For instance, the composition of claim 14 comprises both DGL and LXL; therefore, it is confusing as to why only the one ingredient is referred to by Applicant. Does only the ingredient of LXL have the claimed functional effect? The lack of clarity makes the metes and bounds of the claimed invention uncertain and very confusing.

Claim 23 is rendered vague and indefinite by the phrase "wherein said LXL used for inhibiting growth of transplanted tumors" because it is unclear as to the subject matter Applicant intends to direct the invention. For instance, the composition of claim 14 comprises both DGL and LXL; therefore, it is confusing as to why only the one ingredient is referred to by Applicant. Does only the ingredient of LXL have the claimed

functional effect? The lack of clarity makes the metes and bounds of the claimed invention uncertain and very confusing.

Claim 24 is rendered vague and indefinite by the phrase "wherein said LXL used for inhibiting cancer incidence" because it is unclear as to the subject matter Applicant intends to direct the invention. For instance, the composition of claim 14 comprises both DGL and LXL; therefore, it is confusing as to why only the one ingredient is referred to by Applicant. Does only the ingredient of LXL have the claimed functional effect? The lack of clarity makes the metes and bounds of the claimed invention uncertain and very confusing.

Claim 25 recites the limitation "wherein said PDGL enhancement of immune function, inhibiting oncogenes and cancer incidence" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

Claim 25, line 1, recites the abbreviation "PDGL". Abbreviations in the first instance of claims should be expanded upon with the abbreviation indicated in parentheses. The abbreviations can be used thereafter.

The claims are generally narrative and indefinite, failing to conform with current U.S. practice. They appear to be a literal translation into English from a foreign document and are replete with grammatical and idiomatic errors.

All other cited claims depend directly or indirectly from rejected claims and are, therefore, also, rejected under U.S.C. 112, second paragraph for the reasons set forth above.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is (703) 308-9432. The examiner can normally be reached on Monday through Friday from 7:15 am to 3:45 pm. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196 or the Supervisory Patent Examiner, Brenda Brumback whose telephone number is (703) 306-3220.

Michele C. Flood

MCF

February 6, 2003